Claims

1. Lyophilisate which comprises the active ingredient flupirtine in base form or as physiologically tolerated salt and can be employed for producing a pharmaceutical composition for parenteral administration.

2. Lyophilisate according to claim 1 or 2, comprising at least 100 mg of flupirtine.

3. Lyophilisate according to claim 1, where the physiologically tolerated salt is an acid addition salt of flupirtine.

4. Lyophilisate according to claim 3, where the acid constituent of the salt is selected from the group consisting of gluconic, formic, acetic, propionic, succinic, glycolic, lactic, malic, tartaric, citric, ascorbic, maleic, fumaric, hydroxymaleic, pyruvic, phenylacetic, benzoic, p-aminosalicylic, embonic, methanesulphonic, ethanesulphonic, hydroxyethanesulphonic, ethylenesulphonic, halobenzenesulphonic, toluenesulphonic, naphthalenesulphonic, sulphanilic and hydrochloric acids.

5. Lyophilisate according to claim 3 or 4, where the acid constituent of the salt is present in an amount of from 60 mg to 650 mg, based on 100 mg of flupirtine.

6. Lyophilisate according to claim 5, where the acid constituent is present in an amount of from 200 mg to 400 mg, based on 100 mg of flupirtine.

7. Lyophilisate according to any of claims 1 to 6, additionally comprising at least one cake-forming agent.

8. Lyophilisate according to claim 7, where the cake-forming agent is mannitol, sucrose or glycine.

9. Lyophilisate according to claim 7 or 8, where the cake-forming agent is present in an amount of from 10 mg to 1000 mg, based on 100 mg of flupirtine.

10. Lyophilisate according to claim 9, where the cake-forming agent is present in an amount of from 30 mg to 300 mg, based on 100 mg of flupirtine.

11. Lyophilisate according to any of claims 1 to 10, additionally comprising at least one antioxidant.

12. Lyophilisate according to claim 11, where the antioxidant is sodium bisulphite or ascorbic acid.

13. Lyophilisate according to claim 11 or 12, where the antioxidant is present in an amount of from 0.5 mg to 10 mg, based on 100 mg of flupirtine.

14. Lyophilisate according to claim 13, where the antioxidant is present in an amount of from 2 mg to 5 mg, based on 100 mg of flupirtine.

15. Lyophilisate according to any of claims 1 to 14, additionally comprising a detergent.

16. Lyophilisate according to claim 15, where the detergent is a polyvinylpyrrolidone.

17. Lyophilisate according to claim 15 or 16, where the detergent is present in an amount of from 10 mg to 150 mg, based on 100 mg of flupirtine.

18. Lyophilisate according to claim 17, where the detergent is present in an amount of from 10 mg to

50 mg, based on 100 mg of flupirtine.

19. Lyophilisate according to any of claims 1 to 18, where the pharmaceutical composition for parenteral administration is a solution for injection or solution for infusion.

20. Use of a flupirtine lyophilisate according to any of claims 1 to 19 for producing a pharmaceutical composition for parenteral administration.

21. Use according to claim 20, where the lyophilisate is dissolved in an aqueous medium and/or an organic solvent, and the pharmaceutical composition for parenteral administration is obtained.

22. Use according to claim 21, where the lyophilisate is dissolved in water for injections.

23. Use according to claim 21, where the lyophilisate is dissolved in a buffer solution.

24. Use according to claim 21, where the lyophilisate is dissolved in a water/solvent mixture.

25. Use according to any of claims 21 to 24, where the lyophilisate is dissolved at room temperature.

26. Process for producing a flupirtine-containing pharmaceutical composition for parenteral administration, where a flupirtine-containing lyophilisate according to any of claims 1 to 19 is dissolved in an aqueous medium and/or an organic solvent, and a liquid pharmaceutical composition ready for use is obtained.

27. Process according to claim 26, where the

lyophilisate is dissolved in water for injections.

28. Process according to claim 26, where the lyophilisate is dissolved in a buffer solution.

29. Process according to claim 26, where the lyophilisate is dissolved in a water/solvent mixture.

30. Process according to any of claims 26 to 29, where the lyophilisate is dissolved at room temperature.

31. Process according to any of claims 26 to 30, where the pharmaceutical composition for parenteral administration is a solution for injection.

32. Process according to claim 31, where the solution for injection can be administered intravenously.

33. Process according to claim 32, where the lyophilizate is dissolved in from 3 to 20 ml, preferably 9 to 15 ml, of water for injections to prepare the solution for injection which can be administered intravenously.

34. Process according to claim 31, where the solution for injection can be administered intramuscularly.

35. Process according to claim 34, where the lyophilisate is dissolved in 3 ml of water for injections to prepare the solution for injection which can be administered intramuscularly.

36. Process according to any of claims 26 to 30, where the pharmaceutical composition for parenteral administration is a solution for infusion.

37. Process for producing a flupirtine-containing

lyophilisate according to any of claims 1 to 19, comprising

a) preparation of a flupirtine solution by adding flupirtine base to an aqueous medium and dissolving therein, and

b) freeze drying of the resulting flupirtine solution.

38. Process according to claim 37, where the flupirtine solution is prepared in water.

39. Process according to claim 37, where the flupirtine solution is prepared in an aqueous acid solution.

40. Process according to claim 39, where the acid solution is prepared by dissolving an acid selected from the group consisting of gluconic, formic, acetic, propionic, succinic, glycolic, lactic, malic, tartaric, citric, ascorbic, maleic, fumaric, hydroxymaleic, pyruvic, phenylacetic, benzoic, p-aminosalicylic, embonic, methanesulphonic, ethanesulphonic, hydroxyethanesulphonic, ethylenesulphonic, halobenzenesulphonic, toluenesulphonic, naphthalenesulphonic, sulphanilic and hydrochloric acids in water.

41. Process according to any of claims 38 to 40, where the aqueous medium used to dissolve the flupirtine base is heated to a temperature above room temperature, and then the flupirtine base is added.

42. Process according to claim 41, where the aqueous medium is heated to 30°C to 90°C.

43. Process according to claim 42, where the aqueous medium is heated to 70°C.

44. Process according to any of claims 37 to 43, where the flupirtine base is added while stirring to the, preferably heated, aqueous medium and is dissolved therein by stirring.

45. Process according to any of claims 37 to 44, where the prepared flupirtine solution is filtered before freeze drying.

46. Process according to claim 45, where a filter with a pore width of 0.2 □m is employed for the filtration.

47. Process according to any of claims 37 to 46, where the flupirtine solution is dispensed after filtration into freeze-drying bottles, and the latter are then provided with freeze-drying stoppers.

48. Process according to any of claims 37 to 47, where the flupirtine solution is stored at -45°C.

49. Process according to any of claims 37 to 48, where the freeze drying comprises a main drying and an after-drying.

50. Process according to claim 49 where the main drying takes place at a temperature of from -37°C to -23°C under a pressure of from 10 to 100 mbar.

51. Process according to claim 49 or 50, where the after-drying takes place at a temperature of 27°C under a pressure of 0.0001 mbar.

52. Process according to any of claims 37 to 51, where the bottles containing the lyophilisate after the freeze drying are closed under a nitrogen atmosphere.

53. Liquid flupirtine-containing pharmaceutical composition for parenteral administration, which can be prepared by dissolving a flupirtine-containing lyophilisate according to any of claims 1 to 19.